UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

13-1056

ANTICANCER, INC.,
Plaintiff-Appellant,

v.

PFIZER, INC.,
Defendant-Appellee,

and

CROWN BIOSCIENCE, INC.,
Defendant-Appellee,

and

DOES 1 10,
Defendants.

Appeal from the United States District Court for the Southern District of California in case no. 11-CV-0107
Judge Janis L. Sammartino

MANDATE

In accordance with the judgment of this Court, entered October 20, 2014, and pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure, the formal mandate is hereby issued.

FOR THE COURT

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

cc: Olga Berson
Richard Alan Clegg
Clerk of Court, Southern District of California (San Diego)
J. James Li
Stanley Joseph Panikowski III

Matthew D. Valenti
Richard de Bodo

United States Court of Appeals for the Federal Circuit

ANTICANCER, INC.,
Plaintiff-Appellant,

v.

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Defendants.

2013-1056

Appeal from the United States District Court for the Southern District of California in No. 11-CV-0107, Judge Janis L. Sammartino.

Decided: October 20, 2014

RICHARD A. CLEGG, Law Office of Richard Clegg, of San Diego, California, argued for plaintiff-appellant.

RICHARD DE BODO, Bingham McCutchen LLP, of Santa Monica, California, argued for defendant-appellee Pfizer, Inc. With him on the brief was OLGA BERSON. Of counsel on the brief was STANLEY J. PANIKOWSKI, DLA Piper US LLP, of San Diego, California.

JING JAMES LI, LiLaw Inc., of Los Altos, California, argued for defendant-appellee Crown Bioscience, Inc.

Before NEWMAN, REYNA, and TARANTO, *Circuit Judges.*

NEWMAN, *Circuit Judge.*

This litigation concerns patents owned by AntiCancer, Inc. on technology related to the imaging of gene expression using a green fluorescent protein linked to a gene promoter. The fluorescent protein is derived from a species of green-glowing jellyfish named *Aequorea victoria*. The patented inventions are described as useful for drug discovery and evaluation in cancer control and treatment.

Appeal is from the district court's summary judgment of noninfringement entered not on the substantive merits of any issue raised in the complaint, but on a procedural aspect at the threshold of the litigation arising from application of the Patent Local Rules of the Southern District of California. The district court imposed a fee-shifting sanction as a condition of permitting AntiCancer to supplement the Preliminary Infringement Contentions that the district court found defective under Patent Local Rule 3.1. The court ordered that AntiCancer may supplement its Contentions, provided that it concurrently pay the attorney fees and costs incurred by the defendants in connection with their motion for summary judgment related to the Contentions. AntiCancer objected to this condition, and the district court entered summary judg-

ment of noninfringement and duly dismissed the complaint with prejudice. For the reasons we shall discuss, we conclude that the fee-shifting condition was improperly imposed; the judgment based thereon is vacated.

BACKGROUND

On January 19, 2011, AntiCancer filed a complaint against Pfizer, Inc. in the United States District Court for the Southern District of California, with counts for breach of license agreement, breach of the duty of good faith and fair dealing, and unjust enrichment. The complaint recited that AntiCancer, in a contractual arrangement initially with Wyeth Pharmaceuticals, later acquired by Pfizer, disclosed technology relating to fluorescent proteins and their DNA linkage and imaging in mammals, and the technology's use in cancer drug evaluation and treatment.

After the complaint was filed, AntiCancer came upon several publications authored by scientists at Pfizer and Crown Bioscience, Inc. AntiCancer stated that these publications show the use of AntiCancer's technology and infringement of AntiCancer's patents, and requested permission to amend the complaint by adding counts for patent infringement and adding Crown Bioscience as a defendant. The district court granted the motion on November 8, 2011.

On September 21, 2011, the district court held a case management conference, and on that same date the court issued a "Case Management Conference Order Regulating Discovery and Other Pretrial Proceedings," *AntiCancer, Inc. v. Pfizer Inc.*, No. 11CV107 (S.D. Cal. Sept. 21, 2011), ECF No. 13. The Order provided that: "On or before November 14, 2011, Plaintiff shall serve on all parties a 'Disclosure of Asserted Claims and Preliminary Infringement Contentions,'" in accordance with the Patent Local Rules. *Id.* at 1-2. The Order also set the discovery schedule, with claim construction discovery to be completed by

March 26, 2012, fact discovery to be completed by September 4, 2012, and expert discovery to be completed by October 29, 2012. *Id.* at 8, 11.

On November 9, 2011, AntiCancer filed a First Amended Complaint adding Crown Bioscience as a defendant and adding patent infringement counts. AntiCancer filed its "Disclosure of Asserted Claims and Preliminary Infringement Contentions" on November 14, 2011, as required by the Case Management Conference Order. This document drew primarily on the scientific publications of Pfizer and Crown Bioscience, and consisted of 22 pages, including 18 pages of patent claim charts. The Contentions stated that AntiCancer "reserves the right to amend or supplement its identification of asserted claims, accused instrumentalities, and priority dates, as well as its claim charts, based on further investigation and discovery." J.A. 83-84. On January 31, 2012, the deadline for completing fact discovery was extended to December 4, 2012, and the deadline for expert discovery was extended to January 29, 2013. Am. Case Mgmt. Conf. Order, *AntiCancer* (S.D. Cal. Jan. 31, 2012), ECF No. 32.

On March 12, 2012, Pfizer filed a motion for summary judgment on the patent infringement counts, stating that the Preliminary Infringement Contentions were defective because the "charts are missing claim limitations for each and every claim of each asserted patent, and/or do not identify specifically how Pfizer allegedly practiced each element of the asserted claims." Pfizer's Notice of Mot. & Mot. Summ. J. at 1, *AntiCancer* (S.D. Cal. Mar. 12, 2012), ECF No. 38. Crown Bioscience joined this motion. AntiCancer responded that its Preliminary Infringement Contentions complied with the Patent Local Rules and that the presentations in the claim charts associated the claim elements or steps with a designated portion of the scientific publications of Pfizer and Crown Bioscience. AntiCancer also filed with its opposition brief the declara-

tion of Dr. Robert M. Hoffman, the founder and President of AntiCancer, who explained how a person skilled in this field of science would understand the claim terms and their relation to the Pfizer and Crown Bioscience publications.

The district court found the information in the claim charts deficient as to three claim elements, and authorized AntiCancer to supplement its Preliminary Infringement Contentions but required that AntiCancer concurrently pay the defendants' attorney fees and costs related to the summary judgment motion.[1] The district court gave the defendants fourteen days in which to submit an accounting of their attorney fees and costs and gave AntiCancer fourteen days thereafter in which to file amended Preliminary Infringement Contentions and concurrently pay the defendants' attorney fees and costs, or to "object [to the] conditions for amendment, in which event summary judgment will be granted in Defendants' favor." Dist. Ct. Op. at 15-16. AntiCancer objected to the fees/costs condition,[2] and the district court entered summary judgment of noninfringement.[3]

On July 16, 2012, the district court entered a Judgment in a Civil Case, stating "IT IS ORDERED AND ADJUDGED that summary judgment is hereby granted in favor of Defendant Crown Bioscience, Inc. on the fourth

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[1] *AntiCancer, Inc. v. Pfizer Inc.*, No. 11CV107 (S.D. Cal. June 1, 2012), ECF No. 63 ("*District Court Opinion*") (conditional order granting summary judgment of noninfringement).

[2] Notice of Objection to Court's Conditions for Amendment, *AntiCancer* (S.D. Cal. June 29, 2012), ECF No. 73.

[3] *AntiCancer* (S.D. Cal. July 2, 2012), ECF No. 74 (order entering summary judgment on patent infringement claims).

and fifth claims for relief in AntiCancer's Second Amended Complaint." *AntiCancer* (S.D. Cal. July 16, 2012), ECF No. 80.[4]

The parties then settled the contract claims and filed a "Joint Motion and Stipulation of Voluntary Dismissal, with Prejudice." *AntiCancer* (S.D. Cal. Sept. 26, 2012), ECF No. 85. Upon the parties' joint stipulation, the district court dismissed AntiCancer's Second Amended Complaint with prejudice.[5] AntiCancer then filed its Notice of Appeal, wherein AntiCancer stated it was appealing "from the judgment entered in this action on July 16, 2012."[6]

AntiCancer argues on appeal that the fee-shifting condition and its consequences was a sanction, that the sanction was unwarranted, and that the summary judgment based on the condition was improper. AntiCancer states that it provided all information available to it at the time it filed its Contentions, that it complied with the Patent Local Rules, that there was no bad faith or other sanctionable behavior, and that further details of the defendants' practice of the claimed inventions required discovery of the unpublished laboratory procedures of Pfizer and Crown Bioscience. AntiCancer also states that its pleadings met the requirements of the Federal Rules of Civil Procedure and that, even without supplementation,

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[4] We note that the fourth claim for relief in AntiCancer's Second Amended Complaint is against Pfizer only, and the fifth claim for relief is against Pfizer and Crown Bioscience. Second Am. Compl. 9-10, *AntiCancer* (S.D. Cal. June 22, 2012), ECF. No. 72.

[5] Order Granting Joint Mot. & Stipulation of Voluntary Dismissal, with Prejudice, *AntiCancer* (S.D. Cal. Sept. 28, 2012), ECF No. 86.

[6] Notice of Appeal, *AntiCancer* (S.D. Cal. Oct. 26, 2012), ECF No. 87.

its Preliminary Infringement Contentions complied with the Patent Local Rules. AntiCancer appeals from the requirement for payment of the defendants' attorney fees and costs as a condition for continuing the litigation.

DISCUSSION

A. Standard of Review

The grant of summary judgment is reviewed without deference. *See Flex–Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1357 (Fed. Cir. 2006). Summary judgment is appropriate when there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).

A district court's application of its local rules is reviewed on the standard of abuse of discretion. *See O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366-67 (Fed. Cir. 2006). The district court's exercise of its disciplinary authority is reviewed on the standard of abuse of discretion. *Chambers v. NASCO, Inc.*, 501 U.S. 32, 55 (1991); *see also In re Keegan Mgmt. Co. Sec. Litig.*, 78 F.3d 431, 436 (9th Cir. 1996). Abuse of discretion may be established when the court commits a clear error of judgment in weighing the relevant facts or exercises its discretion based upon an error of law or clearly erroneous factual findings. *See, e.g.*, *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1353 (Fed. Cir. 2008); *United States v. Hinkson*, 585 F.3d 1247, 1262 (9th Cir. 2009).

In *O2 Micro*, this court discussed when and whether Federal Circuit law or regional circuit law applies to issues arising under patent local rules, and concluded that it depends on whether the issue is of substantive patent law or of regional procedure. 467 F.3d at 1364 ("There is an important distinction between local rules of general applicability, which by definition are not unique to patent law and where we apply regional circuit law,

and local rules that only apply to patent cases." (footnote omitted)).

The question of whether a filing under the Patent Local Rules needs supplementation may involve substantive patent law, but the question of whether fee-shifting is an appropriate condition for such supplementation is primarily a matter of discipline under the court's inherent authority, not substantive patent law. *See Baldwin Hardware Corp. v. FrankSu Enter. Corp.*, 78 F.3d 550, 560-62 (Fed. Cir. 1996); *see also Monsanto Co. v. E.I. Du Pont de Nemours & Co.*, 748 F.3d 1189, 1196 (Fed. Cir. 2014).

The federal courts have the inherent powers that "'are necessary to the exercise of all others.'" *Roadway Express, Inc. v. Piper,* 447 U.S. 752, 764 (1980) (quoting *United States v. Hudson*, 7 U.S. 32, 34 (1812)). The Supreme Court has observed that action "in bad faith, vexatiously, wantonly, or for oppressive reasons" may incur sanctions in the form of attorney fees under the court's inherent powers. *Alyeska Pipeline Serv. Co. v. Wilderness Soc'y*, 421 U.S. 240, 258-59 (1975) (quotation omitted). Invocation of the district court's inherent powers is a matter of regional circuit law, rather than Federal Circuit law. *See Monsanto*, 748 F.3d at 1196 ("When reviewing the imposition of sanctions under a district court's inherent powers, we apply the law of the regional circuit in which the district court sits . . . .").

Under Ninth Circuit precedent, "[b]efore awarding sanctions under its inherent powers . . . the court must make an explicit finding that counsel's conduct 'constituted or was tantamount to bad faith.'" *Primus Auto. Fin. Servs., Inc. v. Batarse*, 115 F.3d 644, 648 (9th Cir. 1997) (quoting *Roadway Express*, 447 U.S. at 767); *see also Yagman v. Republic Ins.*, 987 F.2d 622, 628 (9th Cir. 1993) ("Courts may not invoke these [inherent] powers

without a 'specific finding of bad faith.'" (quoting *United States v. Stoneberger*, 805 F.2d 1391, 1393 (9th Cir. 1986))). This rigid imposition that district courts make an explicit finding of bad faith is justified under Ninth Circuit law because of the "very potency [of] inherent powers." *Yagman*, 987 F.2d at 628.

Here, the district court's conditional fee-shifting sanction appears to be grounded in the court's inherent powers relating to the "general conduct of the litigation," rather than on any specific infraction such as violation of 28 U.S.C. §1927 or Rule 11. *Primus Auto.*, 115 F.3d at 648; *see id.* ("Although the district court failed to specify the authority for its order, we can deduce the source of its power for purposes of our review. . . . [W]e will assume that the court relied on its inherent powers."); *see also Jones v. Williams*, 68 Fed. App'x 857, 859 (9th Cir. 2003) ("Since the district court did not specify the authority under which sanctions were imposed, we assume that the court was exercising its inherent powers . . . ."); *Irwin v. Colletti*, No. 98-15019, 1999 WL 109662, at *1 n.3 (9th Cir. Feb. 26, 1999) ("The district court did not specify the authority for its fee award. . . . [W]e conclude that the district court relied upon its inherent powers in awarding fees . . . .").

Of significance to our review is the Ninth Circuit's requirement of an explicit finding of bad faith before imposing a sanction. We note the Ninth Circuit's recognition of the importance of this requirement, *see Primus Auto.*, 115 F.3d at 649-50, as well as the Supreme Court's observance of the gravity of district courts invoking their inherent authority, *see, e.g.*, *Roadway Express*, 447 U.S. at 764 ("Because inherent powers are shielded from direct democratic controls, they must be exercised with restraint and discretion.").

We apply this guidance to the "factual and legal prerequisites to the exercise of this [inherent] power," *Zambrano v. City of Tustin*, 885 F.2d 1473, 1478 (9th Cir. 1989), surrounding Patent Local Rule 3.1 as here applied, including the asserted deficiencies of AntiCancer's submissions.

B. Patent Local Rule 3.1

The purpose of preliminary infringement contentions as required by Patent Local Rule 3.1 is to assist the court and guide the parties in focusing on potentially dispositive issues, providing a framework for discovery and generally facilitating the proceedings. *See, e.g.*, *Network Caching Tech. LLC v. Novell, Inc.*, No. C-01-2079, 2003 WL 21699799, at *5 (N.D. Cal. Mar. 21, 2003) ("PICs [preliminary infringement contentions] are not meant to provide a forum for litigation of the substantive issues; they are merely designed to streamline the discovery process.").

It appears undisputed that AntiCancer's complaint complied with the Federal Rules of Civil Procedure. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (complaint must contain sufficient facts to plausibly show that complainant may be entitled to relief); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (allegations in complaint must "plausibly suggest[]" the accused conduct to "raise a reasonable expectation that discovery will reveal evidence" of such accused conduct). The issue on appeal relates to the fee-shifting sanction imposed as a condition of supplementing AntiCancer's Preliminary Infringement Contentions under Patent Local Rule 3.1. Rule 3.1 states:

> Not later than fourteen (14) days after the Initial Case Management Conference, a party claiming patent infringement must serve on all parties a "Disclosure of Asserted Claims and Preliminary Infringement Contentions." Separately for each

opposing party, the "Disclosure of Asserted Claims and Preliminary Infringement Contentions" must contain the following information:

a. Each claim of each patent in suit that is allegedly infringed by each opposing party;

b. Separately for each asserted claim, each accused apparatus, product, device, process, method, act, or other instrumentality ("Accused Instrumentality") of each opposing party of which the party is aware. This identification must be as specific as possible. Each product, device and apparatus must be identified by name or model number, if known. Each method or process must be identified by name, if known, or by any product, device, or apparatus which, when used, allegedly results in the practice of the claimed method or process;

c. A chart identifying specifically where each element of each asserted claim is found within each Accused Instrumentality, including for each element that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function;

d. Whether each element of each asserted claim is claimed to be literally present and/or present under the doctrine of equivalents in the Accused Instrumentality;

e. For any patent that claims priority to an earlier application, the priority date to which each asserted claim allegedly is entitled; and

f. If a party claiming patent infringement asserts that its own apparatus, product, device, process, method, act, or other instrumentality practices the claimed invention, the party must identify,

> separately for each asserted claim, each such apparatus, product, device, process, method, act, or other instrumentality that incorporates or reflects that particular claim.

The Southern District of California adopted Patent Local Rules similar to those of the Northern District of California and refers to decisions of the Northern District as authority for their interpretation.[7] *See NessCap Co., Ltd. v. Maxwell Techs., Inc.*, No. 07cv0704, 2008 WL 152147, at *1 (S.D. Cal. Jan. 16, 2008) ("[B]ecause the Southern District's Patent Local Rule 3.4(a) is similar in all material respects to the corresponding patent local rules promulgated by the Northern District of California . . . this Court relies on published and unpublished precedent from that court[] as persuasive authority."); *see also Zest IP Holdings, LLC v. Implant Direct Mfg., LLC*, No. 10cv0541, 2013 WL 1626111, at *5 (S.D. Cal. Apr. 15, 2013) (looking to Northern District case law with respect to Patent Local Rule 3.1); *Ameranth, Inc. v. Pizza Hut, Inc.*, No. 12cv1659, 2013 WL 3894880, at *5 (S.D. Cal. July 26, 2013) (same); *accord* Dist. Ct. Op. at 5 n.4 ("This Order cites to out-of-district case law interpreting patent local rules promulgated by other districts that are substantively similar to our own as persuasive authority." (citing *NessCap*, 2008 WL 152147, at *1)); *id.* at 6. We observed in *O2 Micro* that the Northern District's rules were designed to "'require parties to crystallize their theories of the case early in the litigation' so as to 'prevent the shifting sands approach to claim construction.'" 467 F.3d at 1364 (quoting *Atmel Corp. v. Info. Storage Devices,*

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[7] The Southern District of California adopted amended patent local rules on February 8, 2013. This decision is directed to the rules in effect at the time of these proceedings.

Inc., No. C 95-1987, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)).

The district court cited the explanation by the Northern District of California that "'infringement contentions need not prove infringement' but must 'outline a plaintiff's theories of infringement.'" Dist. Ct. Op. at 6 (quoting *Data Retrieval Tech., LLC v. Sybase*, No. C 08-5481, 2009 U.S. Dist. LEXIS 129454, at *8 (N.D. Cal. Sept. 11, 2009)). In *Shared Memory Graphics LLC v. Apple, Inc.*, the Northern District explained that "Rule 3-1 does not necessarily require the patent holder to produce evidence of infringement." 812 F. Supp. 2d 1022, 1025 (N.D. Cal. 2010). In *Genentech, Inc. v. Trustees of University of Pennsylvania*, the Northern District summarized:

> The purpose of the disclosure rules is to further the goal of full, timely discovery and provide all parties with adequate notice of and information with which to litigate their cases. In analyzing disclosures in the parallel context of infringement contentions pursuant to Patent L.R. 3–1, courts have distinguished between the required identification of the precise element of any accused product alleged to practice a particular claim limitation, and every evidentiary *item of proof* showing that the accused element did in fact practice the limitation.

No. C 10–2037, 2012 WL 424985, at *1 (N.D. Cal. Feb. 9, 2012) (citations and quotations omitted).

We apply this guidance to determine whether the sanction here imposed as a condition of supplementing the Rule 3.1 Preliminary Infringement Contentions was an abuse of discretion.

C. The Preliminary Infringement Contentions

AntiCancer states that its Contentions showed its theories of infringement, provided notice of the infor-

mation to be obtained by discovery, and complied with the letter and purpose of Patent Local Rule 3.1. AntiCancer's Rule 3.1 filing stated that "[t]he attached Asserted Claims and Preliminary Contentions Charts . . . identify to the extent possible based on information currently in AntiCancer's possession where each element of each asserted claim is found within each accused instrumentality of which AntiCancer is aware." J.A. 85. AntiCancer states that its "infringement theories were as crystallized as they could be" before AntiCancer could "possibly have taken any discovery to support its infringement claims and to learn the actual details of the defendants' internal research activities." Appellant Br. at 8-9, 13.

The patents are United States Patent No. 6,649,159 (the '159 patent) and Reissue Patent No. RE 39,337 (the '337 patent). The '159 patent is for a method of monitoring gene expression using fluorescence imaging. Claim 1 recites:

> 1. A method to monitor the ability of a promoter to promote expression in an animal of an endogenous gene that is controlled by said promoter, which method comprises:
>
> a) delivering, to an animal, cells containing a nucleic acid encoding a fluorophore operatively linked to the promoter of said endogenous gene whose ability to promote expression is to be analyzed; and
>
> b) observing the presence, absence or intensity of the fluorescence generated by said fluorophore at various locations in said animal by whole-body external fluorescent optical imaging,
>
> whereby the ability of said promoter to promote expression is monitored, and
>
> wherein said fluorophore is a protein that is autofluorescent such that no substrates or cofactors are needed for it to fluoresce.

With its Contentions for the '159 patent, AntiCancer incorporated the Pfizer publication entitled "Defects in Embryonic Development of EGLN1/PHD2 Knockdown Transgenic Mice are Associated with Induction of Igfbp in the Placenta," published at 390 *Biochemical and Biophysical Research Communications* 370 (2009). This article describes experiments using green fluorescent protein imaging of gene expression in mouse embryos. In its claim charts, AntiCancer included Figure 2 from that publication, captioned "Embryoplacenta l effects of the localization of intense (+++) GFP fluorescence in EGNLI RNAi hairpin treated embryos," showing mouse embryos with these effects.

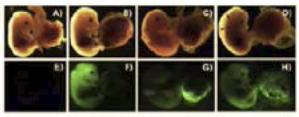
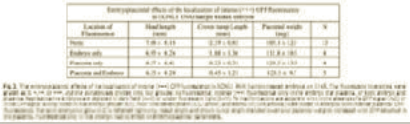
The '337 patent is directed to a mouse model in a process called "surgical orthotopic implantation," in which fragments of human tumors are implanted into the corresponding organ of a living mouse. Claim 1 of the '337 patent as reissued recites:

> 1. A nude mouse model for progression of human neoplastic disease, the progression of said disease being characterized by growth of a primary tumor site and metastasis to secondary tumor sites,
>
> wherein said mouse has histologically intact human neoplastic tissue of at least 1 mm in size transplanted onto an organ of said mouse which corresponds to the human organ from which said tissue is originally obtained;
>
> and has sufficient immuno-deficiency to allow said transplanted neoplastic tissue to grow at said primary site and metastasize to said secondary tumor sites, so as to mimic the progression of the neoplastic disease including the metastatic behavior of said neoplastic disease in humans.

With its Contentions for the '337 patent, AntiCancer included a Pfizer-Crown Bioscience poster presentation

entitled "Establishment of the Orthotopic Primary Human Hepatocellular Carcinoma Model for Oncology Drug Discovery," presented at the 20th Asia Pacific Cancer Conference in November 2009. This presentation described mouse models in evaluation of the Pfizer cancer drug Sutent.

For each patent claim identified as infringed in AntiCancer's Preliminary Infringement Contentions, and each element of each claim, AntiCancer identified a specific portion of the relevant publication. This description was presented for each independent claim and each dependent claim in suit. The defendants criticized the completeness of this description; for example, the defendants criticized AntiCancer's presentation for Claim 1 of the '159 patent, shown as marked up by the defendants and argued to the district court as demonstrating that the claim charts were deficient:

CLAIM LANGUAGE AntiCancer US Patent No. 6,649,159	**IDENTIFICATION OF ELEMENTS OF CLAIM FOUND WITHIN ACCUSED INSTRUMENTALITIES**
1. A method to monitor the ability of a promoter to promote expression in an animal of an endogenous gene that is controlled by said promoter, which method comprises: a) delivering, to an animal, cells containing a nucleic acid encoding a fluorophore operatively linked to the promoter of said endogenous gene whose ability to promote expression is to be analyzed; and b) observing the presence, absence or intensity of the fluorescence generated by said fluorophore at various locations in said animal by whole-body external fluorescent optical imaging, whereby the ability of said promoter to promote expression is monitored, and wherein said fluorophore is	"Defects in embryonic development of EGLN1/PHD2 knockdown transgenic mice are associated with induction of lgfbp in the placenta" a paper published by Pfizer scientists Timothy S. Fisher, Diane M. Nadeau, Jeffrey L. Stock, Anne S. Klein, Anthony J. Milici, Daniel Morton, Margeret B. Wilhelms, William H. Brissette, and Baiyong Li details experiments performed using GFP imaging of mouse embryos. AntiCancer hereby incorporates the full text of that paper. Below is a screenshot of Figure 2 of that paper.  
a protein that is autofluorescent such that no substrates or cofactors are needed for it to fluoresce.	Below is the full text of this claim with each element of the claim followed by the evidence of the accused instrumentality found within the paper in brackets and boldface. 1. A method to monitor the ability of a promoter to promote expression in an animal of an endogenous gene that is controlled by said promoter, which method comprises: a) delivering, to an animal, cells containing a nucleic acid encoding a fluorophore **[Fig. 2; "we generated transgenic mice expressing EGLN1 shRNA"]** operatively linked to the promoter of said endogenous gene whose ability to promote expression is to be analyzed **[Fig. 2; "To examine the developmental effect of EGLN1 we generated transgenic mice expressing EGLN1 shRNA."; "The localization and intensity of GFP fluorescence in conceptuses from both treatment groups was varied."]**; and b) observing the presence, absence or intensity of the fluorescence generated by said fluorophore at various locations in said animal by whole-body external fluorescent optical imaging **[Fig. 2; "The localization and intensity of GFP fluorescence in conceptuses from both treatment groups was varied."]**, whereby the ability of said promoter to promote expression is monitored **[Fig. 2: "The localization and intensity of GFP fluorescence in conceptuses from both treatment groups was varied."]**, and wherein said fluorophore is a protein that is autofluorescent such that no substrates or cofactors are needed for it to fluoresce **[Fig. 2;"GFP fluorescence in EGNL1 RNAi hairpin treated embryos"]**.

Pfizer's Mem. P. & A. Supp. Mot. Summ. J. Noninfringement Based on Defective Infringement Contentions 11, *AntiCancer* (S.D. Cal. Mar. 12, 2012), ECF No. 38-1.

The district court held that AntiCancer's claim charts did not provide all of the information the Patent Local Rules require. The district court held that the claim charts were deficient as to three elements: the "promoter monitoring" and "delivering cells" elements of the '159 patent, and the "metastasis to a second site" element of the '337 patent.

AntiCancer argues that the Contentions and claim charts adequately showed the connection between these claim elements and the information in the Pfizer and Crown Bioscience publications, and showed, prima facie, the presence of these elements in the accused activities. AntiCancer states that the degree of specificity in its Contentions and claim charts was in accordance with the Patent Local Rules, and further specificity and detail will require discovery of the defendants' non-public, internal activities. AntiCancer stresses that the Patent Local Rules contemplate that discovery will follow from the Preliminary Infringement Contentions, and that it is not expected or intended that the Contentions must provide complete proof of infringement before the patentee has a meaningful opportunity to conduct discovery.

On the role of discovery in the specificity of the Preliminary Infringement Contentions, it cannot be ignored that AntiCancer's Preliminary Contentions were required to be filed within two months of the district court's Case Management Conference Order and just five days after AntiCancer filed its First Amended Complaint adding the infringement counts and party-defendant Crown Bioscience, with nearly ten months remaining until the close of fact discovery pursuant to the original Case Management Conference Order. The commentary on preliminary infringement contentions in those district courts that

have adopted similar local rules is that the contentions precede discovery and are intended to facilitate discovery. This court, in *O2 Micro*, mentioned "the broad discovery regime under the Federal Rules of Civil Procedure, especially given the particular importance of discovery in complex patent cases." 467 F.3d at 1365.

We note the limiting language of Patent Local Rule 3.1, requiring the plaintiff to identify the accused products, instrumentalities, or acts "of which the party is aware"; and to be "as specific as possible," with the name or model number of the accused product, device, or apparatus "if known." These requirements harmonize the Local Rule with the discovery provided by the Federal Rules and warrant consideration when reviewing the district court's fee-shifting sanction.

Turning to the three claim elements for which the district court found AntiCancer's Preliminary Infringement Contentions deficient, we review compliance with Patent Local Rule 3.1 in the context of the condition the district court imposed on AntiCancer's ability to supplement the Contentions. In the end, considering the language and purposes of the Local Rule, and the record of what AntiCancer disclosed in its Contentions and the limited, specific criticisms of the Contentions' sufficiency, we conclude that there is no reasonable basis for making the finding of bad faith that would be required to sustain the fees sanction, without which summary judgment here is improper. Indeed, we do not see how revised Contentions could be insufficient if AntiCancer added to them the brief explanations it provided in its opposition to summary judgment.

1. promoter monitoring

Each asserted '159 patent claim includes the clause "whereby the ability of said promoter to promote expression is monitored." *See* '159 patent col. 24 l. 44 - col. 26 l. 12. The district court observed that "in support of its

allegation of infringement" of the promoter monitoring element, AntiCancer's Contentions identified Figure 2 and the Pfizer publication's statement that "[t]he localization and intensity of GFP fluorescence in conceptuses from both treatment groups was varied." The district court concluded that "[o]n its face, the text from the paper says nothing about 'promoters' or 'monitoring.'" Dist. Ct. Op. at 8. The court found that the citations to portions of the Pfizer publication, or the incorporation of its full text, did not "suppl[y] sufficient information for how Pfizer allegedly practiced the Promoter Monitoring element," Dist. Ct. Op. at 8, and stated that "AntiCancer needs to connect the dots for how Pfizer's research . . . reads on the asserted claim language," *id.* at 9.

AntiCancer states that further specificity would be obtained with discovery and faults the district court for granting summary judgment before there was claim construction "or a comparison of the properly construed claims to the accused methods." Appellant Br. at 19. *See, e.g.*, *Ameranth, Inc. v. Papa John's USA, Inc.*, 946 F. Supp. 2d 1049, 1057-61 (S.D. Cal. 2013) (denying motion for summary judgment and holding that defendant's allegation that preliminary infringement contentions lacked sufficient specificity "turns the issue into one of claim construction rather than sufficiency of the PICs [preliminary infringement contentions]," and was thus premature); *Network Caching*, 2003 WL 21699799, at *4 ("Patent LR 3–1 does not require [the plaintiff] to produce evidence of infringement . . . .").

AntiCancer continues to stress that its Preliminary Infringement Contentions stated that the disclosures and claim charts "identify to the extent possible based on information currently in AntiCancer's possession where each element of each asserted claim is found within each accused instrumentality of which AntiCancer is aware." Appellant Br. at 24-25. AntiCancer had argued in its brief opposing the motion for summary judgment that "it

would be clear to any competent scientist or even a layman, that measuring the 'intensity' of any process is another way of saying that the process is being 'monitored,'" and provided the declaration of its founder and President, Dr. Robert M. Hoffman, explaining this science. The Hoffman declaration states that "it is impossible to measure the intensity of a process without monitoring it, since intensity refers to a degree of measurement which is monitored over time." Decl. Robert M. Hoffman at 3, *AntiCancer* (S.D. Cal. Apr. 2, 2012), ECF No. 40-1. Dr. Hoffman explained that the Pfizer publication

> clearly indicates that the promoter was monitored in this experiment. Fluorescence intensity was graded as either "0, +, ++, or +++." Therefore, expression of GFP varied from "0" at the lowest end to "+++" at the highest end, which means the activity (intensity) of the promoter linked to GFP was varied. The scientist conducting this experiment could only have rated the varying intensity of the GFP promoter by monitoring it.

Id.

The district court apparently gave weight to the inclusion of additional explanation in AntiCancer's opposition brief and the Hoffman declaration, and remarked that AntiCancer was "capable" of making the "connection" between the Pfizer publication and the claim elements. Dist. Ct. Op. at 9. The court observed that AntiCancer's brief contained more details than its Contentions, and stated:

> Indeed, in its opposition brief [AntiCancer] makes this connection: "[I]t is the signal of GFP fluorescence which indicates the *activity of the promoter*, and the 'localization and intensity' of such fluorescence, and thereby of the promoter, is determined

> by viewing or imagining the subject over time – in other words, by monitoring it."

Id. (quoting AntiCancer's brief in opposition to motion for summary judgment of noninfringement). The district court thus suggested that this information should have been included in the Preliminary Infringement Contentions. AntiCancer does not object to such inclusion, but objects to the fee-shifting condition placed on this inclusion.

As we review the nature of the deficiencies that were found by the district court, and the condition imposed on AntiCancer's supplementation of the Contentions, AntiCancer reasonably argues that its "infringement theories were as crystallized as they could be under the circumstances, five (5) days after it had filed its First Amended Complaint with its infringement claims." Appellant Br. at 13. AntiCancer argues that there was no uncertainty as to the subject matter that was charged with infringement, and that the supplemental information sought by the district court would be obtained by discovery, as contemplated by the Patent Local Rules, as well as the broad discovery regime provided for by the Federal Rules of Civil Procedure. The district court referred to the requirement that "the degree of specificity under Local Rule 3–1 must be sufficient to provide reasonable notice to the defendant why the plaintiff believes it has a 'reasonable chance of proving infringement.'" *Shared Memory Graphics*, 812 F. Supp. 2d at 1025 (quoting *View Eng'g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 986 (Fed. Cir. 2000)). However, the question on appeal is not whether the district court properly required additional specificity in these Contentions, but whether a fee-shifting sanction was appropriately attached to the court's authorization to supplement the Contentions.

Ninth Circuit precedent negates the imposition of a fee-shifting sanction absent an explicit finding of bad

faith. Although the district court described the Contentions as "woefully insufficient" and "vague," and described AntiCancer as "act[ing] unreasonably" and "disingenuous" in submitting the Contentions, Dist. Ct. Op. at 14, there is no explicit finding of bad faith. Indeed, the district court's observation that AntiCancer's brief in opposition to the motion for summary judgment and the Hoffman declaration might meet the court's concerns weighs against any inference of bad faith. We thus conclude that a fee-shifting sanction conditioned on AntiCancer's supplementation for the "promoter monitoring" element cannot be sustained.

2. delivering cells

The "delivering cells" element appears in each of the asserted '159 patent claims, as "delivering, to an animal, cells containing a nucleic acid encoding a fluorophore operatively linked to the promoter." *See* '159 patent col. 24 l. 44 - col. 26 l. 12. AntiCancer's claim charts refer to the Pfizer publication and the publication's statement that "we generated transgenic mice expressing EGLN1 shRNA."

EGLN1 shRNA denotes the mouse expression of a known genetic trait. The district court observed AntiCancer's argument to be that

> it is a basic scientific concept that in order to have a transgenic mouse, cells must have been delivered. In other words, inherent within the statement 'we generated transgenic mice expressing EGLN1 shRNA' is the concept that cells containing a nucleic acid encoding a fluorophore were delivered to an animal.

Dist. Ct. Op. at 11 n.8.

The defendants argued that the Pfizer publication did not show the "delivering cells" element, but merely described the fluorescent mice used by Pfizer. AntiCancer

responded that "[a]lthough the Pfizer Article does not explicitly state that GFP [green fluorescent protein]-labeled cells were delivered, such delivery is so implicit that it needs no statement . . . [because] it could not be done any other way than by 'delivering cells,' a basic scientific concept that should be well understood by a company with Pfizer's expertise." AntiCancer Opp'n Mot. Summ. J. at 5, *AntiCancer* (S.D. Cal. Apr. 2, 2012), ECF No. 41. AntiCancer argued that identification of the information in the Pfizer publication by the AntiCancer Preliminary Infringement Contentions and claim charts satisfied the requirements of the Patent Local Rules, for the step of "delivering cells" would be "apparent to a competent scientist, or even a layman." *Id.*

The district court compared the claim language "delivering, to an animal, cells containing a nucleic acid encoding a fluorophore," with the language of the Pfizer publication "we generated transgenic mice expressing EGLN1 shRNA," and stated:

> As Pfizer correctly notes, the cited sentence does not mention cells. It does not mention delivering cells, fluorophores, or nucleic acids encoding fluorophores to animals. The quoted sentence only refers to animals (i.e., 'transgenic mice') with a particular genetic trait (i.e., 'expressing' a particular gene—'EGLN1 shRNA').

Dist. Ct. Op. at 10 (internal quotations and citation omitted). The district court concluded that "AntiCancer in no way attempts to make a connection between the sentence provided and the claim language, and the PICs additionally draw no connection between Figure 2 and the relevant claim language." *Id.* However, the district court observed that AntiCancer had elaborated on this element in its opposition brief, the court stating: "Essentially, Anticancer argues that because its [sic] common knowledge that GFP comes from jellyfish—not mice—'the

GFP gene had to have been delivered.'" Dist. Ct. Op. at 11 (quoting AntiCancer Opp'n Mot. Summ. J. at 5).

The district court ruled that the Contentions for the "delivering cells" element did not "suppl[y] sufficient information for how Pfizer allegedly practiced this element. . . . cit[ing] to a single sentence from the Pfizer paper as evidence that Pfizer infringed this element." Dist. Ct. Op. at 10. The court stated that "the connections between the claim language and the 'evidence of the accused instrumentality' that AntiCancer makes in its opposition brief need to be set forth in the PICs, even if they are 'basic scientific concepts' that are generally known or publicly available." Dist. Ct. Op. at 11 (citing *Linex Techs., Inc. v. Belkin Int'l, Inc.*, 628 F. Supp. 2d 703, 709 (E.D. Tex. 2008)).

The district court faulted the Preliminary Infringement Contentions for failing to provide sufficient "evidence" of the accused instrumentalities and "information" about how Pfizer practiced the "delivering cells" element. Dist. Ct. Op. at 10-11. AntiCancer argues that, as precedent has established, the purpose of the Contentions is to outline the theories of infringement and streamline discovery, not to provide proof of infringement. *See O2 Micro*, 467 F.3d at 1364 (the Contentions are intended to "crystallize [the infringement] theories . . . so as to prevent the shifting sands approach to claim construction" (internal quotation marks omitted)).

We conclude that, in view of AntiCancer's presentation of the "delivering cells" element at this stage, and applying the law of the Ninth Circuit concerning the standards for fee-shifting, the district court exceeded its discretionary authority in imposing a fee-shifting sanction as a condition of proceeding with the litigation.

3. metastasis to a second site

The third element for which the district court held the Preliminary Infringement Contentions to be deficient is "metastasis to a second site" in the '337 patent claims. The claims are directed to "a nude mouse model for progression of human neoplastic disease, the progression of said disease being characterized by growth of a primary tumor site and metastasis to secondary tumor sites, wherein said mouse has . . . sufficient immuno-deficiency to allow said transplanted neoplastic tissue to grow at said primary site and metastasizing to said secondary tumor sites." '337 patent col. 11 ll. 13-67. AntiCancer's Contentions recited the following text from the defendants' poster presentation as corresponding to this element:

> "Tumor fragments derived from patient tumor tissues were surgically implanted into the left lobe of nude mouse liver"; "Sutent treatment significantly inhibited orthotopic HCC tumor growth; Plasma samples were collected at different time points for alpha-feto-protein (AFP) measurement. At termination, tumors were excised from liver and their weights and sizes were recorded"; "In addition, histological analysis confirmed that orthotopically implanted primary human tumors maintained their histopathological characteristics."

Disclosure of Asserted Claims and Preliminary Infringement Contentions at 95-96, *AntiCancer* (S.D. Cal. Mar. 12, 2012), ECF 38-4.

The defendants argued that the passages quoted from their poster presentation were insufficient to establish a connection between this claim element and the defendants' activities, because the poster does not specifically describe the implanted tumor as metastasizing to a second location. AntiCancer responded that the '337 patent claims require sufficient mouse immuno-deficiency

to "allow said transplanted neoplastic tissue to grow at said primary site and metastasize to said secondary tumor sites," and that the defendants' publications showing growth of the tumor at the site of implantation "is direct evidence that the mice used were sufficiently immuno-deficient to *allow* for growth at the primary site and for metastasis at secondary sites." AntiCancer Opp'n Mot. Summ. J. at 4-6. The district court stated:

> AntiCancer has left out the essential connection between the claim language and the allegedly infringing acts. *How* does the growth of the tumor at the primary site provide 'direct evidence' that the mice were sufficiently immuno-deficient to allow for metastasis to secondary sites? By skipping this essential connection, AntiCancer leaves Defendants—and the Court—guessing at how the patent was allegedly infringed, hindering Defendants' ability to prepare an effective defense.

Dist. Ct. Op. at 13.

AntiCancer states that its Contentions were not deficient, and that the district court's question of "*how*" tumor growth relates to immuno-deficiency transcends the requirement of Local Rule 3.1, to simply provide "a chart identifying specifically where each element of each asserted claim is found within each Accused Instrumentality." AntiCancer also states that it identified the activities meeting the "metastasis to a second site" element, and that persons of skill in this science would readily understand that the tumor control described in the defendants' publication also related to metastasis.

In *Network Caching*, the Northern District court explained that the Preliminary Infringement Contentions "are not meant to provide a forum for litigation of the substantive issues; they are merely designed to streamline the discovery process." 2003 WL 21699799, at *5. The Preliminary Infringement Contentions do not need to

include proof or direct evidence of infringement, as the various decisions on the Patent Local Rules have explained.

We again conclude that the district court's fee-shifting condition for supplementing the Contentions was unwarranted, applying the Ninth Circuit's requirement of bad faith for imposition of sanctions as discussed, e.g., in *Primus Automotive*, 115 F.3d at 648.

CONCLUSION

Summary judgment is appropriate when there is no reasonable possibility that the non-movant could prevail upon proper pleadings and a full and fair trial. *See* Fed. R. Civ. P. 56; *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). Here, the district court granted summary judgment based on its finding that AntiCancer's Preliminary Infringement Contentions were deficient and because AntiCancer objected to the fee-shifting sanction imposed as a condition of supplementing the Contentions.

When a complaint meets the standards of the Federal Rules, and there has been no reasonable opportunity for discovery and evidentiary development of the issues, it is rarely appropriate to summarily decide the merits against the complainant. We need not intrude upon the district court's authority to require supplementation of the Preliminary Infringement Contentions when such supplementation may assist the procedures of trial. However, exercise of a court's inherent authority to levy a sanction as a condition of supplementing the Contentions requires conduct that "constituted or was tantamount to bad faith." *Roadway Express*, 447 U.S. at 767. There is no finding, and there is no basis for a finding, of such impropriety here.

We conclude that the district court exceeded its discretion in imposing the condition of payment of the defendants' attorney fees and costs in order to permit

AntiCancer to supplement its Preliminary Infringement Contentions. We vacate the condition, and the summary judgment based thereon. The case is remanded for further proceedings.

VACATE AND REMANDED